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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/030,137   | 03/11/2002  | Kelvin Stott         | P67518USO           | 8173             |
| 136  | 7590        | 03/26/2004           | EXAMINER            |                  |
| JACOBSON HOLMAN PLLC<br>400 SEVENTH STREET N.W.<br>SUITE 600<br>WASHINGTON, DC 20004 |             |                      | LIU, SAMUEL W       |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1653                |                  |

DATE MAILED: 03/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/030,137 | <b>Applicant(s)</b><br>STOTT, KELVIN |  |
|                              | <b>Examiner</b><br>Samuel W Liu      | <b>Art Unit</b><br>1653              |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 January 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date: _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____  | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Preliminary amendment filed 28 January 2002, which amends claims 3-4, 6-7, 10-11, 13, 15-17, 19, 21-23, 25-27 and 29-44 has been entered. The following Office action is applicable to the pending claims 1-45.

#### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-28 and 43, drawn to a composition comprising a  $\beta$ -strand forming peptide having characteristics (i) the said peptide comprising a sequence of at least four consecutive amino acid residues that are  $\beta$ -strand formers, and (ii) the said peptide comprising amino acids which side chains undergo  $N\alpha$ -modification .

Group II, claims 29, 31 and 36, drawn to a method of inhibiting aggregation of target  $\beta$ -strands, aggregation of monomer proteins or aggregation of protein subunits comprising contacting the Group I composition with said  $\beta$ -strands, monomer proteins or protein subunits.

Group III, claims 30, 32, 34 and 37-38, drawn to a method of making a medicament comprising the Group I composition for (i) inhibiting aggregation of target  $\beta$ -strands, aggregation of monomer proteins or aggregation of protein subunits, or an enzyme oligomerization (i.e., aggregation), or refolding denatured/aggregated protein.

Group IV, claim 33, drawn to a method of promoting refolding of denatured or aggregated proteins comprising contacting the Group I composition with said proteins.

Group V, claims 35 and 44-45, drawn to a method of treating or diagnosing a disease state caused by protein aggregation comprising using the Group I composition.

Group VI, claim 39, drawn to a method of indicating the presence of diagnosing a  $\beta$ -structure comprising exposing a test sample to the Group I composition.

Group VII, claim 40, drawn to a method of preparing an agent comprising the Group I composition for indicating the presence of diagnosing a  $\beta$ -structure.

Group VIII, claim 41, drawn to a method of performing a protein denaturation chromatography comprising covalently attaching the Group I composition to a solid matrix or resin, running a test sample through chromatographic column, and separating desired product from said sample.

Group IX, claim 42, drawn to a combinational library comprising the Group I composition.

The invention listed as Groups I –IV do not related to a single general invention concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The instant claim 1 is obvious over Quibell M. et al. (*J. Chem. Soc. Perkin. Trans* (1995) 1, 2019-2024). Prior to the effective filing date of the instant application, Quibell *et al.* teach a composition comprising a  $\beta$ -strand forming peptide having characteristics set forth in the claim, e.g., the said peptide comprising a sequence of at least four consecutive amino acid residues that are  $\beta$ -strand formers, and the said peptide comprising amino acids which side chains undergo N $\alpha$ -modification (see especially abstract and the structure shown on page 2020. The above Harris et al. teaching meets the limitation set forth in claim 1 of the current application. Thus, the claimed composition does not constitute a special technical feature linking all claims, as defined by PCT Rule 13.2 and 37 CFR 1.475(a), as a single contribution over the art, and a holding of lack of unity is therefore proper.

Additional Election

Regardless of the elected group, applicant is required under 35 US 121 (1) to elect a single disclosed composition to which claims are restricted.

If Group V is elected, applicant is required to elect one disease state from claim 45 because the recites disease states in the claim are pathologically distinct/different, e.g., type II diabetes mellitus and Alzheimer's disease are distinct from one another in view of their pathological mechanism and rout of treatment.

The response to the election requirement should also identify the claims readable thereon as directed to the elected invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicants are advised that reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is (571) 272-0949. The examiner can normally be reached Monday-Friday 9:00 -5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

*swl*

Samuel Wei Liu, Ph.D.  
March 11, 2003

*Karen Cochrane Carlson*

KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER